METHOD AND APPARATUS FOR ATTACHING CONNECTIVE TISSUES TO BONE USING A KNOTLESS SUTURE ANCHORING DEVICE

Background of the Invention

This invention relates generally to methods and apparatus for attaching soft tissue to bone, and more particularly to anchors and methods for securing connective tissue, such as ligaments or tendons, to bone. The invention has particular application to arthroscopic surgical techniques for reattaching the rotator cuff to the humeral head, in order to repair the rotator cuff.

It is an increasingly common problem for tendons and other soft, connective tissues to tear or to detach from associated bone. One such type of tear or detachment is a "rotator cuff" tear, wherein the supraspinatus tendon separates from the humerus, causing pain and loss of ability to elevate and externally rotate the arm. Complete separation can occur if the shoulder is subjected to gross trauma, but typically, the tear begins as a small lesion, especially in older patients.

To repair a torn rotator cuff, the typical course today is to do so surgically, through a large incision. This approach is presently taken in almost 99% of rotator cuff repair cases. There are two types of open surgical approaches for repair of the rotator cuff, one known as the "classic open" and the other as the "mini-open". The classic open approach requires a large incision and complete detachment of the deltoid muscle from the acromion to facilitate exposure. The cuff is debrided to ensure suture attachment to viable tissue and to create a reasonable edge approximation. In addition, the humeral head is abraded or notched at the proposed soft tissue to bone reattachment point, as healing is enhanced on a raw bone surface. A series of small diameter holes, referred to as "transosseous tunnels", are "punched" through the bone laterally from the abraded or notched surface to a point on the outside surface of the greater tuberosity, commonly a distance of 2 to 3 cm. Finally, the cuff is sutured and secured to the bone by pulling the suture ends through the transosseous tunnels and tying them together using the bone between

two successive tunnels as a bridge, after which the deltoid muscle must be surgically reattached to the acromion. Because of this maneuver, the deltoid requires postoperative protection, thus retarding rehabilitation and possibly resulting in residual weakness. Complete rehabilitation takes approximately 9 to 12 months.

The mini-open technique, which represents the current growing trend and the majority of all surgical repair procedures, differs from the classic approach by gaining access through a smaller incision and splitting rather than detaching the deltoid. Additionally, this procedure is typically performed in conjunction with arthroscopic acromial decompression. Once the deltoid is split, it is retracted to expose the rotator cuff tear. As before, the cuff is debrided, the humeral head is abraded, and the so-called "transosseous tunnels", are "punched" through the bone or suture anchors are inserted. Following the suturing of the rotator cuff to the humeral head, the split deltoid is surgically repaired.

Although the above described surgical techniques are the current standard of care for rotator cuff repair, they are associated with a great deal of patient discomfort and a lengthy recovery time, ranging from at least four months to one year or more. It is the above described manipulation of the deltoid muscle together with the large skin incision that causes the majority of patient discomfort and an increased recovery time.

Less invasive arthroscopic techniques are beginning to be developed in an effort to address the shortcomings of open surgical repair. Working through small trocar portals that minimize disruption of the deltoid muscle, a few surgeons have been able to reattach the rotator cuff using various bone anchor and suture configurations. The rotator cuff is sutured intracorporeally and an anchor is driven into bone at a location appropriate for repair. Rather than thread the suture through transosseous tunnels which are difficult or impossible to create arthroscopically using current techniques, the repair is completed by tying the cuff down against bone using the anchor and suture. Early results of less invasive techniques are

encouraging, with a substantial reduction in both patient recovery time and discomfort.

Unfortunately, the skill level required to facilitate an entirely arthroscopic repair of the rotator cuff is inordinately high. Intracorporeal suturing is clumsy and time consuming, and only the simplest stitch patterns can be utilized. Extracorporeal knot tying is somewhat less difficult, but the tightness of the knots is difficult to judge, and the tension cannot later be adjusted. Also, because of the use of bone anchors to provide a suture fixation point in the bone, the knots that secure the soft tissues to the anchor by necessity leave the knot bundle on top of the soft tissues. In the case of rotator cuff repair, this means that the knot bundle is left in the shoulder capsule where it can be felt by the patient postoperatively when the patient exercises the shoulder joint. So, knots tied arthroscopically are difficult to achieve, impossible to adjust, and are located in less than optimal areas of the shoulder. Suture tension is also impossible to measure and adjust once the knot has been fixed. Consequently, because of the technical difficulty of the procedure, presently less than 1% of all rotator cuff procedures is of the arthroscopic type, and is considered investigational in nature.

Another significant difficulty with current arthroscopic rotator cuff repair techniques is shortcomings related to currently available suture anchors. Suture eyelets in bone anchors available today, which like the eye of a needle are threaded with the thread or suture, are small in radius, and can cause the suture to fail at the eyelet when the anchor is placed under high tensile loads.

There are various bone anchor designs available for use by an orthopedic surgeon for attachment of soft tissues to bone. The basic commonality between the designs is that they create an attachment point in the bone for a suture that may then be passed through the soft tissues and tied, thereby immobilizing the soft tissue. This attachment point may be accomplished by different means. Screws are known for creating such attachments, but suffer from a number of disadvantages, including their tendency to loosen over time, requiring a second procedure to later

remove them, and their requirement for a relatively flat attachment geometry.

Another approach is to utilize the difference in density in the cortical bone (the tough, dense outer layer of bone) and the cancellous bone (the less dense, airy and somewhat vascular interior of the bone). There is a clear demarcation between the cortical bone and cancellous bone, where the cortical bone presents a kind of hard shell over the less dense cancellous bone. The aspect ratio of the anchor is such that it typically has a longer axis and a shorter axis and usually is pre-threaded with a suture. These designs use a hole in the cortical bone through which an anchor is inserted. The hole is drilled such that the shorter axis of the anchor will fit through the diameter of the hole, with the longer axis of the anchor being parallel to the axis of the drilled hole. After deployment in to the cancellous bone, the anchor is rotated 90° so that the long axis is aligned perpendicularly to the axis of the hole. The suture is pulled, and the anchor is seated up against the inside surface of the cortical layer of bone. Due to the mismatch in the dimensions of the long axis of the anchor and the hole diameter, the anchor cannot be retracted proximally from the hole, thus providing resistance to pull-out. These anchors still suffer from the aforementioned problem of eyelet design that stresses the sutures.

Still other prior art approaches have attempted to use a "pop rivet" approach. This type of design requires a hole in the cortical bone into which a split shaft is inserted. The split shaft is hollow, and has a tapered plug leading into its inner lumen. The tapered plug is extended out through the top of the shaft, and when the plug is retracted into the inner lumen, the tapered portion causes the split shaft to be flared outwardly, ostensibly locking the device into the bone.

Other methods of securing soft tissue to bone are known in the prior art, but are not presently considered to be feasible for shoulder repair procedures, because of physicians' reluctance to leave anything but a suture in the capsule area of the shoulder. The reason for this is that staples, tacks, and the like could possibly fall out and cause injury during movement. As a result of this constraint, the attachment point often must be located at a less than ideal position. Also, the tacks

or staples require a substantial hole in the soft tissue, and make it difficult for the surgeon to precisely locate the soft tissue relative to the bone.

As previously discussed, any of the anchor points for sutures mentioned above require that a length of suture be passed through an eyelet fashioned in the anchor and then looped through the soft tissues and tied down to complete the securement. Much skill is required, however, to both place the sutures in the soft tissues, and to tie knots while working through a trocar under endoscopic visualization.

There have been attempts to solve some of the problems that exist in current anchor designs. One such approach is disclosed in U.S. Patent No. 5,324,308 to Pierce. In this patent, there is disclosed a suture anchor that incorporates a proximal and distal wedge component having inclined mating faces. The distal wedge component has two suture thread holes at its base through which a length of suture may be threaded. The assembly may be placed in a drilled hole in the bone, and when tension is placed on the suture, the distal wedge block is caused to ride up against the proximal wedge block, expanding the projected area within the drilled hole, and locking the anchor into the bone. This approach is a useful method for creating an anchor point for the suture, but does not in any way address the problem of tying knots in the suture to fix the soft tissue to the bone.

The problem of placing sutures in soft tissues and tying knots in an endoscopic environment is well known, and there have been attempts to address the problem and to simplify the process of suture fixation. One such approach is disclosed in U.S. Patent No. 5,383,905 to Golds et al. The patent describes a device for securing a suture loop about bodily tissue that includes a bead member having a longitudinal bore and an anchor member adapted to be slidably inserted within the bore of the bead member. The anchor member includes at least two axial compressible sections which define a passageway to receive two end portions of a suture loop. The axial sections collapse radially inwardly upon insertion of the anchor member within the bore of the bead member to securely wedge the suture

end portions received within the passageway.

Although the Golds et al. patent approach utilizes a wedge-shaped member to lock the sutures in place, the suture legs are passing through the bore of the bead only one time, in a proximal to distal direction, and are locked by the collapsing of the wedge, which creates an interference on the longitudinal bore of the anchor member. Also, no provision is made in this design for attachment of sutures to bone. The design is primarily suited for locking a suture loop, such as is used for ligation or approximation of soft tissues.

An approach that includes bone attachment is described in U.S. Patent No. 5,584,835 to Greenfield. In this patent, a two part device for attaching soft tissue to bone is shown. A bone anchor portion is screwed into a hole in the bone, and is disposed to accept a plug that has been adapted to receive sutures. In one embodiment, the suture plug is configured so that when it is forced into its receptacle in the bone anchor portion, sutures that have been passed through an eyelet in the plug are trapped by friction between the wall of the anchor portion and the body of the plug portion.

Although there is some merit to this approach for eliminating the need for knots in the attachment of sutures to bone, a problem with being able to properly set the tension in the sutures exists. The user is required to pull on the sutures until appropriate tension is achieved, and then to set the plug portion into the bone anchor portion. This action increases the tension in the sutures, and may garrot the soft tissues or increase the tension in the sutures beyond the tensile strength of the material, breaking the sutures. In addition, the minimal surface area provided by this anchor design for pinching or locking the sutures in place will abrade or damage the suture such that the suture's ability to resist load will be greatly compromised.

A disclosure that incorporates bone attachment and eliminates knot tying is set forth in U.S. Patent No. 5,702,397 to Goble et al. One embodiment, in particular, is shown in Figure 23 of that patent and includes a bone anchor that has

a threaded body with an inner cavity. The cavity is open to one end of the threaded body, and joins two lumens that run out to the other end of the threaded body. Within the cavity is disposed a gear, journaled on an axle. A length of suture is threaded through one lumen, around the gear, and out through the other lumen. A ball is disposed within the cavity to ride against a tapered race and ostensibly lock the suture in place. What is not clear from the patent disclosure is how the force D shown as the tension in the suture would lock the ball into the race. Although this embodiment purports to be a self-locking anchor adapted for use in blind holes for fixing sutures into bone, the construct shown is complicated, and does not appear to be adequate to reliably fixate the suture.

What is needed, therefore, is a new approach for repairing the rotator cuff or fixing other soft tissues to bone, wherein suture tension can be adjusted and possibly measured, the suture anchor resides completely below the cortical bone surface, there is no requirement for the surgeon to tie a knot to attach the suture to the bone anchor, and wherein the procedure associated with the new approach is better for the patient, saves time, is uncomplicated to use, and easily taught to practitioners having skill in the art.

Summary of the Invention

The present invention solves the problems outlined above by providing innovative bone anchor and connective techniques which permit a suture attachment which lies entirely beneath the cortical bone surface. In the present state of the art, the sutures which are passed through the tissues to be attached to bone typically are threaded through a small eyelet incorporated into the head of the anchor and then secured by tying knots in the sutures. Endoscopic knot tying is an arduous and technically demanding task. Therefore, the present invention discloses devices and methods for securing sutures to a bone anchor without the requirement of knot tying.

In accordance with one aspect of the present invention, a knotless suture anchor apparatus for anchoring a length of suture with respect to a body cavity comprises an anchor body having an anchoring structure for fixing the anchor body within a body cavity, and a suture locking plug. The anchor body has proximal and distal ends, and a lumen opening at the proximal end. A suture pulley fixed with respect to the anchor body is provided such that a length of suture may be introduced into the lumen from the proximal end, looped around pulley, and passed out of lumen through the proximal end. The suture locking plug is movable within the lumen from a first position to a second position. Desirably, the suture locking plug and lumen cooperate such that the suture locking plug does not interfere with axial movement of the length of suture in the first position and interferes with axial movement of the length of suture in the second position, preferably by compressing the length of suture against the anchor body.

In a preferred embodiment, the anchor body is generally tubular and the lumen opens at the distal end as well as at the proximal end. The distal end of the anchor body may be discontinuous at one side thereof wherein a slot extends in a proximal direction from the discontinuity to a slot end. The suture locking plug includes a proximal section that fits within the lumen and a distal stop extending radially outward into the slot that interferes with the anchor body at the end of the slot and limits proximal movement of the plug with respect thereto. An actuation rod may be removably attached to the proximal end of the suture locking plug and project out of the proximal end of the anchor body so as to be usable to displace the locking plug within the lumen. Desirably, the actuation rod includes a point of tensile weakness permitting the rod to be detached from the locking plug.

The suture pulley may be formed in a sidewall of lumen. For example, where the anchor body is tubular, the suture pulley is desirably disposed at a distal end of the tubular body. In a preferred embodiment, the lumen opens at the distal end of the tubular body and a pulley comprises a rod at the open distal end transverse to the lumen axis. The rod may rotate with respect to the anchor body,

or may be fixed. Instead of a rod, the pulley may comprise a bridge formed between two spaced apertures at the distal end of the tubular body.

In another aspect of the present invention, a knotless suture anchor apparatus for anchoring a length of suture with respect thereto includes an anchor body and a suture locking plug. The anchor body has proximal and distal ends and a lumen open at the proximal end. A suture pulley fixed with expect to the anchor body permits a length of suture to be introduced into the lumen from the proximal end, looped around the pulley, and passed out of lumen through the proximal end. The suture locking plug is movable within the lumen from a first position which does not interfere with axial movement of the length of suture to a second position that compresses the length of suture against the anchor body and interferes with axial movement of the length of suture.

In accordance with a further aspect of the present invention, a knotless suture anchor apparatus for anchoring a length of suture with respect to a body cavity comprises an anchor body having an anchoring structure for fixing the anchor body within a body cavity. The anchor body has proximal and distal ends, and a lumen opening at both the proximal and distal ends, the lumen having a diameter that permits a length of suture to be passed therethrough. A suture locking plug comprises a shaft axially displaceable within the lumen from a first position which does not interfere with axial movement of the length of suture to a second position that interferes with axial movement of the length of suture. A stop is provided that positively interferes with proximal movement of the suture locking plug with respect to the anchor body.

The present invention also provides a method of securing soft tissue with respect to a body cavity without knots. The method includes passing a length of suture through soft tissue so that a loop of suture material is embedded in the soft tissue resulting in two free ends. An anchor body having an open proximal end and a lumen is provided, wherein a pulley is fixed with respect to the anchor body. The two free ends of length of suture are passed into lumen of the anchor body through

the open proximal end and looped around pulley. The two free ends are extended out of lumen through the open proximal end. The anchor body is fixed with respect to a body cavity, and the loop of suture material is tightened by pulling one or both of the two free ends of the length of suture. Finally, the two free ends of the length of suture are fastened with respect to the anchor body without knots.

In the described method, the soft tissue may be a tendon and the body cavity may be formed in bone. In a particular preferred operation, the tendon is the rotator cuff tendon, and the bone is the humerus. The step of fixing the anchor body with respect to the body cavity may include forming a body cavity, passing the anchor body therein, and radially extending anchoring structure on the anchor body. In a preferred embodiment, the anchoring structure is provided on a proximal end of the anchor body and interferes with the cortical layer of the bone to prevent proximal removal of the anchor body from the cavity. The method may include providing a suture locking plug movable within the lumen from a first position which does not interfere with axial movement of the two free ends of the length of suture to a second position that compresses the two free ends of the length of suture against the lumen and interferes with axial movement thereof. The proximal actuation rod that extends out of the lumen from the proximal end of the anchor body may be coupled to the suture locking plug, wherein the method includes displacing the actuation rod in the proximal direction with respect to the anchor body, and desirably severing the actuation rod from the suture locking plug after the step of fastening.

Now, it is to be understood that the above described invention is particularly suited to locking sutures that have been passed through soft tissues and are to be anchored to bone. The creation of an anchor point within the bone is outside the scope of this invention, although many alternative methods of anchoring suture to bone are contemplated. For example, some currently preferred methods are discussed in U.S. Patent Application Serial No. 09/616,802, entitled *Method & Apparatus for Attaching Connective Tissues to Bone Using a Suture Anchoring*

Device, filed on July 14, 2000. The referenced application is commonly assigned with the present application, and is incorporated by reference in its entirety herein. Other prior art anchors, such as screws, moly bolts, and pop rivets may be adapted for use with the present invention as well.

The invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in conjunction with the accompanying illustrative drawing.

Brief Description of the Drawings

Figure 1A is a partial sectional view through the left shoulder of a human as seen from the front showing the use of a minimally invasive soft tissue to bone attachment system of the present invention;

Figure 1B is an enlarged sectional view taken within the circle denoted 1B in Figure 1A;

Figures 2A-2D are enlarged sectional views of the use of the soft tissue to bone attachment system of Figure 1A to reattach a rotator cuff tendon;

Figures 3A-3C are partial longitudinal sectional views through a distal end of an exemplary soft tissue to bone attachment system of the present invention;

Figure 4A is a perspective view of a combined suture locking portion and bone anchor structure of the soft tissue to bone attachment system of the present invention, showing a locking plug disengaged from an anchor body;

Figure 4B is a partial longitudinal sectional view of the combined suture locking portion and bone anchor structure taken along line 4B-4B of Figure 4A;

Figure 4C is an end elevational view of the combined suture locking portion and bone anchor structure taken along line 4C-4C of Figure 4B;

Figure 5 is a perspective view of an anchor body of the combined suture locking portion and bone anchor structure of Figure 6A;

Figure 6 is a top plan view of the combined suture locking portion and bone anchor structure without the locking plug and an attached actuation rod; and

Figure 7A is a perspective view of an exemplary suture locking portion of the soft tissue to bone attachment system of the present invention showing a locking plug disengaged from an anchor body;

Figure 7B is a partial longitudinal sectional view of the suture locking portion taken along line 7B-7B of Figure 7A;

Figure 7C is an end elevational view of the suture locking portion taken along line 7C-7C of Figure 7A;

Figure 8A is a perspective view of the exemplary suture locking portion of the soft tissue to bone attachment system of the present invention showing the locking plug engaged with the anchor body;

Figure 8B is a partial longitudinal sectional view taken along line 8B-8B of Figure 8A;

Figure 8C is an end elevational view taken along line 8C-8C of Figure 8A illustrating the locking plug clamping a length of suture against an inner lumen of the anchor body;

Figure 9A is a side elevational view of the deployed anchor structure relative to the anchor body and locking plug therein;

Figure 9B is an end elevational view of Figure 9B;

Figure 10 is a partial sectional view through the left humeral head of a human as seen from the front showing the use of an alternative minimally invasive soft tissue to bone attachment system of the present invention; and

Figure 11 is a perspective view of a combined suture locking portion and bone anchor structure of the present invention, showing an alternative suture pulley structure.

Description of the Preferred Embodiment

The present invention provides an improved knotless suture anchor apparatus for anchoring a length of suture with respect to a body cavity. In the exemplary embodiment described herein, the apparatus is used to anchor a length

of suture to a bone structure, specifically the humeral bone of the human shoulder. The length of suture is desirably looped through soft tissue, such as a rotator cuff tendon, to approximate and fix the soft tissue with respect to the body cavity (e.g., bone structure). It should be understood, however, that the suture anchor apparatus may be utilized to secure a length of suture to body cavities other than in a bone structure, and may even be used to anchor the suture outside of a body cavity, merely to a predetermined location within the body. In this regard, the preferred apparatus includes an anchor body within which the length of suture may be anchored without knots. If the anchor body is to be implanted within the body cavity, structure on its exterior may also be provided for securing the anchor body therein. In a preferred embodiment, the anchor body is positioned within a pre-formed cylindrical cavity within a bone structure, and a bone anchor deployed from the exterior of the anchor body to hold it within the cavity.

As mentioned, the present invention is particularly well-suited for repairing rotator cuff injuries by re-attaching the rotator cuff tendon to the outside of the humeral head. The invention permits minimally invasive surgeries on such injuries and greatly facilitates rapid and secure fixation of the rotator cuff tendon to the humeral head. It should be understood that the same principles described herein apply to the repair of other injuries in which soft tissue is to be re-attached to a bone structure.

Figures 1A-1BA and 2A-2D are cross-sectional views through the left shoulder of a human as viewed from the front and illustrate the use of an exemplary suture anchor system 20 for repairing a rotator cuff tendon injury. The rotator cuff tendon 22 is shown in its natural positioned overlying the bulbous humeral head 24 of the humerus bone 26. In rotator cuff injuries, the tendon 22 partially or completely separates from its attachment point to the humeral head 24, which point of attachment is typically located along an angled shelf, the greater tuberosity 28. In minimally invasive surgeries to repair the rotator cuff injury, the surgeon threads one or more sutures through the rotator cuff tendon 22 and anchors them to the

greater tuberosity 28. The suture anchor system 20 of the present invention facilitates this latter step of anchoring the sutures to the greater tuberosity 28.

With reference first to Figure 1A, a generally tubular trocar 30 provides a conduit through the soft tissue of the shoulder for the suture anchor system 20 of the present invention. Typically, the surgeon makes an incision or stab wound through the outer dermal layers of sufficient size to permit passage of the trocar 30 through skin and the deltoid muscle into proximity with the humeral head 24. Various trocars and techniques for creating the approach passageway are known and may be utilized with the present invention. In addition, more than one incision and conduit may be necessary to perform the several suturing and anchoring steps.

After establishing one or more direct conduits to the humeral head 24, the surgeon passes a length of suture through the soft tissue of the rotator cuff tendon 22 so that a loop 32 of suture material is embedded therein, as seen in Figure 1B. The two free ends 34a, 34b of the length of suture are withdrawn from the patient and coupled to the suture anchor system 20. The specifics of this coupling and subsequent manipulation of the two free ends of the suture will be described more fully below. For the purpose of explaining the exemplary method of use, it is sufficient to understand that the two free ends 34a, 34b pass into a lumen at the distal end of the suture anchor system 20 and extend through the lumen in a proximal direction to a proximal end of the system to enable fixation or pulling of the suture ends. As seen in Figure 1B, the two free ends 34a, 34b are shown projecting from a proximal end of the system. The system 20 further includes a plurality of concentrically disposed cannulas or tubes as shown that perform the knotless suture anchoring operation. The interrelationship and functioning of these tubes will also be more fully explained below.

The exemplary system 20 as illustrated is particularly suitable for anchoring a suture to a body cavity, specifically the humeral head 24 as shown. When anchoring sutures to such a bone structure, a conventional technique is to first form a blind hole or cavity 40 through the cortical layer 42 and into the soft cancellous

matter 44, as seen in Figures 1A-1B and 2A-2D. The surgeon then positions a suture anchor 46 within the cavity 40 and deploys it such that it cannot be removed from the cavity.

The suture anchor 46 performs two functions: anchoring itself within the body cavity and anchoring the sutures therein. In the illustrated embodiment, the former function is accomplished using an expandable anchoring structure 48 located on the proximal end of the suture anchor 46. The anchoring structure 48 functions like a toggle bolt used in ceiling fixtures, and specifically expands to a larger dimension in the cavity 40 beyond the hard cortical bone 42. In this manner, the suture anchor 46 is prevented from being removed from the cavity 40 once the anchoring structure 48 is deployed. The present invention illustrates a particular anchoring structure 48, although any similar expedient will work. For example, a different toggle-like anchoring structure may be used such as shown in co-pending application Serial Number 09/616,802, filed July 14, 2000, the disclosure of which is hereby expressly incorporated by reference. Alternatively, an anchoring structure that expands into contact with the cancellous matter 44 may be used. In short, the present invention is not considered to be limited by the particular anchoring structure.

The second function of the suture anchor 46 is the anchoring or fixation of the suture with respect to the suture anchor itself, without the use of knots. Desirably, the particular manner of anchoring the suture with respect to the suture anchor 46 permits easy adjustment of the length of suture between the suture anchor and the loop 32 formed in the soft tissue. This adjustment allows the surgeon to establish the proper tension in the length of suture for effective repair of the soft tissue; reattachment of the rotator cuff tendon 22 in the illustrated embodiment. In this regard, Figure 2D shows the fully deployed suture anchor 46 after the free ends 34a, 34b have been placed in tension and locked within the suture anchor. Although not shown, the remaining steps in the procedure involve withdrawing the concentric tubes from the surgical site and severing the free ends

34a, 34b close to the suture anchor 46.

Figures 3A-3C are different partial longitudinal sectional views taken through the exemplary suture anchor system 20 of the present invention. The suture anchor 46 is seen in cross-section disposed in a close-fitting relationship within a delivery tube 50. The delivery tube 50, in turn, may be arranged to slide within a larger tube 52, sometimes known as an introducer tube, that includes a valve (not shown) on a proximal end to prevent fluid leakage therefrom. Alternatively, such a fluid leakage valve may be provided on the proximal end of the trocar 30 seen in Figures 1A-1B.

The suture anchor 46 is defined by a generally tubular anchor body 54 and an inner deployment tube 56 fits closely within a proximal end and is fastened therein. The exemplary suture anchor 46 is shown and described in greater detail below with respect to Figures 4-5. The deployment tube 56 can also be seen on the right side in Figure 3A projecting from the series of concentric tubes, with the free ends 34a, 34b of the length of suture projecting therefrom. A die tube 58 sized intermediate the delivery tube 50 and the deployment tube 56 is arranged for longitudinal displacement over the deployment tube 56. In the illustrated state of the system 20, the suture anchor 46 is undeployed within the delivery tube 50 and the die tube 58 is positioned just proximal to the expandable anchoring structure 48. A further component of the suture anchor system 20 is a suture locking plug 62 having an actuation rod 64 removably attached to a proximal end thereof and extending proximally within the deployment tube 56.

Figures 3A-3C all show the suture loop 32 extending transversely from within the concentric tubes of the suture anchor system 20. In this regard, the delivery tube 50 is provided with an axial slot 51, the deployment tube 56 is provided with an axial slot 57, and the die tube 58 has an axial slot 59. The free ends 34a, 34b of the length of suture pass through these aligned axial slots 51, 57, 59 to the interior of the deployment tube 56 that opens into the lumen 66 of the tubular body 54. The aligned axial slots 51, 57, 59 permit passage of the free ends

34a, 34b into the system 20 from a location midway along the concentric tubes, as indicated in Figures 1-2.

The various described components of the suture anchor system 20 are relatively axially movable to deploy the suture anchor 46. Various means are known to relatively displace concentric tubes a predetermined distance and/or with a predetermined displacement force. For example, the concentric tubes may extend out of the trocar 30 to an actuation device in the form of concentric syringe bodies/finger tabs. Alternatively, the concentric tubes may be attached to relatively movable parts in a gun-type handle, and actuated by triggers or other such levers. It is to be understood therefore that the present invention is not limited by the particular actuation device on its proximal end, and no further description in this regard will be provided.

A more complete understanding of the exemplary suture anchor 46 will be helpful prior to a detailed description of the structure and function of the concentric tubes to deploy the system. In this regard, Figures 4-6 illustrate one embodiment of a suture anchor 46 isolated from the remainder of the system and having the aforementioned tubular anchor body 54 and deployable anchoring structure 48. The anchor body 54 defines a lumen 66 therewithin. Figures 4A and 4B also illustrate the suture locking plug 62 and attached actuation rod 64.

The anchor body 54 has the anchoring structure 48 on its proximal end and a suture pulley 70 disposed in proximity to its distal end. The aforementioned suture loop 32 is schematically illustrated out of the soft tissue for clarity, and it should be understood that this suture loop 32 is embedded in the soft tissue in actual use of the system. The free ends 34a, 34b of the length of suture pass through an angled toggle ring 72 of the anchoring structure 48 and into an open proximal end 74 of the lumen 66 formed within the tubular anchor body 54. The angled toggle ring 72 attaches to the proximal end 74 via a pair of plastically deformable struts 76. Both the toggle ring 72 and struts 76 are initially formed as a projection of the tubular anchor body 54. After continuing in the distal direction

through the lumen of the anchor body 54, the free ends 34a, 34b wrap around the suture pulley 70 and traverse the lumen in the proximal direction to emerge from the angled toggle ring 72 as shown.

As best seen in Figure 4B, the actuation rod 64 extends into an open distal mouth 76 of the anchor body 54 and through the lumen 66 and angled toggle ring 72. The actuation rod 64 and four strands of the length of suture thus share the space within the lumen 66. Because of the relatively smaller size of the actuation rod 64 with respect to the lumen 66, the length of suture may slide axially within lumen without interference. It can therefore be seen that because the suture loop 32 is embedded in soft tissue, pulling on the free ends 34, 34b of the length of suture places the suture loop in tension.

Prior to a more exhaustive description of the function of the locking plug 62 to perform the second function of the suture anchor 46 (i.e., anchoring the length of suture with respect to the suture body 54), use of the concentric tubes to deploy the anchoring structure 48 will be explained. With reference again to Figures 3A-3C, the deployment tube 56 can be seen attached within the lumen 66 of the anchor body 54 using a tab 80. Of course, other means for attaching the deployment tube 56 within the lumen of a body 54 may be provided, but a small tab 80 bent inwardly from the anchor body 54 and welded or otherwise secured to the deployment tube 56 is a suitable expedient. The tab 80 is desirably provided at only one location around the circumferential junction between the deployment tube 56 and lumen 66 to facilitate severing of this connection, although more than one attachment may be provided. The tab 80 thus secures the deployment tube 56 within the anchor body 54 of the suture anchor 46, while both the die tube 58 and actuation rod 64 can freely slide with respect to the anchor body 54.

After positioning the delivery tube 50 in proximity with the preformed body cavity 40 as seen in Figures 1A and 1B, the surgeon advances the deployment tube 56 having the suture anchor 46 attached thereto into the cavity. The suture locking plug 62 and die tube 58 advance along with the deployment tube 56, and the

resulting configuration is seen in Figure 1B.

Using a depth measurement, or visualization technique, the surgeon insures that the suture anchor 46, and in particular the anchoring structure 48, has been inserted past the hard outer layer of cortical bone 42. The anchoring structure is then expanded as seen in Figure 2A. To accomplish this, the die tube 58 contacts the angled toggle ring 72 and forces it into an orientation that is generally perpendicular with respect to the axis of the suture anchor 46. With reference to Figures 3A-3C, the die tube 58 is desirably held stationary while the deployment tube 56 having the suture anchor 46 attached thereto is pulled in a proximal direction. Again, the relative movement of these tubes can be accomplished using a handle or other device exterior to the patient's body. Pulling on the deployment tube 56 forces one side of the angled toggle ring 72 against the generally circular distal mouth of the deployment tube 56 which deforms the struts 76 as the toggle ring 72 moves into a perpendicular orientation.

After the anchoring structure 48 is deployed, further pulling on the deployment tube 56 detaches it from the suture anchor 46. Specifically, the aforementioned welded tab 80 severs at a predetermined pulling force. The die tube 58 remains in place in its fixed position, and provides a reaction force against the suture anchor 46. The deployment tube 56 is then pulled free and retracted out of the way, as indicated in Figure 2B. At this stage, the suture anchor 46 is secured with respect to the body cavity, but the length of suture passing therethrough remains free to be axially displaced.

Now with specific reference to Figures 3A-3C, the path of the length of suture through the suture anchor system 20 will be described. The suture loop 32 is seen projecting upward from the system, but it again should be noted that this loop is embedded in soft tissue in use of the system. The two free ends 34a, 34b extend through an axial slot 90 in the delivery tube 50, and through an axial slot 90 in the deployment tube 56 into lumen 66 of the suture can 46. As best seen in Figure 3C, the free ends pass through the lumen 66 and around the aforementioned pulley 70.

The free ends then travel in a proximal direction through the lumen 66 and through the lumen of the deployment tube 56 to emerge from proximal end of the system. Because the suture loop 32 is embedded in soft tissue, pulling on both of the free ends 34a, 34b, or pulling on one end while holding one fixed, will create tension in the length of suture. The pulley 70 provides relatively little resistance to sliding of the length of suture therearound, and thus this tensioning can be accomplished relatively easily.

In one embodiment, the pulley 70 comprises a pin oriented transversely to the axis of the suture anchor 46 and located along a sidewall thereof. As seen best in Figure 4A, the pin may span an axial slot 100 in a sidewall of the anchor body 54 so that the free ends 34a, 34b of length of suture can pass out through the slot and around the pin. Alternatively, two axially spaced holes with chamfered or rounded edges may be formed in the sidewall of the anchor body 54 through which the free ends 34a, 34b can be threaded. Of course, numerous structures are contemplated that provide the function of the illustrated pin-type pulley 70. Moreover, instead of being a fixed structure, the pulley 70 can be arranged to swivel or otherwise move to facilitate sliding motion of the free ends 34a, 34b therearound. In a specific example, the pin-type pulley 70 can be formed separately from the anchor body 54 and inserted within a pair of facing holes in the edges of the slot 100. In this manner, the pin-type pulley 70 rotates within the holes, thus reducing friction between the free ends 34a, 34b and the pulley.

The step of tensioning the length of suture is seen in Figure 2C, wherein the suture locking plug 62 remains in its initial position spaced from the anchor body 54. Adjustment of the length of the suture between the suture anchor 46 and the loop 32 is very important to ensure proper fixation of the rotator cuff tendon 22 with respect to the humeral head 24. If the suture is pulled too tightly, the rotator cuff tendon 22 may be unduly stressed, and the loop 32 may even pulled free from the tendon. On the other hand, if the suture is too loose, the goal of reattaching the tendon 22 in its proper location will be compromised.

Once the surgeon has established proper tension on the suture, the suture is anchored with suspect to the anchor body 54. This is done by displacing the suture locking plug 62 in a proximal direction so that it is forced into the lumen 66. The plug 62 includes a generally cylindrical shaft 102 with a bullet-shaped proximal nose 104 to help prevent its catching on the distal mouth 78 of the anchor body 54. Proximal displacement of the actuation rod 64 from outside the body causes proximal movement of the attached plug 62.

Figures 7-8 show the anchor body 54 without the aforementioned anchoring structure 48 for clarity. These views illustrate the movement of the suture locking plug 62 into the lumen 66, and consequent locking of the length of suture therein. The diameter of the cylindrical shaft 102 of the plug 62 is sized to be slightly smaller than the inner diameter of the lumen 66. As seen in Figures 8B and 8C, the diameter of the cylindrical shaft 102 is such that it compresses the four strands of the length of suture against the lumen 66. The locking plug 62 is dimensioned to compress or "crush" the length of suture in the lumen 66 and interfere with its axial movement therethrough. The amount of compression may be measured by the amount of pull force on the suture necessary to move it once the plug is in position. Desirably, the pull force is in a range that would exceed the USP (United States Pharmacopeia) Standard knot pull strength (USP 24) of the suture used. In the specific case of #2 braided polyester suture, this knot pull strength is approximately 3.5 Kgf. In practice, however, the knot pull strength of commercially available #2 braided polyester sutures approaches 14 Kgf.

Proximal displacement of the locking plug 62 within the anchor body 54 is desirably limited by a positive stop. In the illustrated embodiment, a stop flange 110 projects outwardly from the cylindrical shaft 102 at its distal end. The stop flange 110 slides within an axial slot 112 at the distal end of the anchor body 54 that terminates at a slot end 114. Although not shown in the figures, proximal movement of the locking plug 62 is ultimately restricted by contact between the stop flange 110 and the slot end 114. Of course, other configurations that provide a

positive stop to proximal movement of the locking plug 62 are contemplated. For example, rather than dimensioning the locking plug 62 to be larger than the lumen 66 of the anchor body 54 (as exhibited by the stop flange 110), a stop surface may project inwardly from the lumen 66 to interfere with movement of the plug 62.

One advantage provided by the present invention is the ability to tighten a suture loop embedded within soft tissue to a predetermined tension, and then locked to the suture within a suture anchor without even slightly altering that tension. As best seen in Figure 8B, the locking plug 62 is shown partly inserted within the tubular body 54 during the step of being pulled proximal by the actuation rod 64 as indicated by the movement arrows 116. The free ends 34a, 34b of the length of suture extend around the pulley 70, having previously been tensioned to a predetermined amount. Proximal movement of the locking plug 62 acts on all four strands of the length of suture within the lumen of the tubular body 54, and thus imparts equal frictional forces to all of the strands tending to urge them in a proximal direction. Because the four strands loop around the pulley 70, with two coming and two going, these frictional forces cancel out such that the free ends 34a, 34b do not migrate within the tubular body 54. Because the pulley 70 and tubular body 54 remain fixed with respect to the suture loop 32 (which is embedded within the soft tissue), the predetermined tension within the loop remains constant during the suture locking step.

In a further example, as seen in Figures 9A and 9B, deformation of the angled toggle ring 72 forces it into an oval shape at the proximal end 74 of the anchor body 54. This oval shape may have a minor dimension that is smaller than the diameter of the cylindrical shaft 102, or more typically the struts 76 may be bent into the path of the shaft 102, thus presenting an interference and a positive stop to the shaft movement. Alternatively, the actuation rod 64 may be bent back upon the exterior surface of the locking plug 62 to form the stop surface.

Once the suture locking plug 62 has been positively stopped, the actuation rod 64 may be detached therefrom. As seen in the figures, the actuation rod 64

extends within a through bore in the cylindrical shaft 102 and includes a frangible point 120 in that bore. The segment of the actuation rod distal from this frangible point 120 is secured within the bore in a conventional manner, such as with crimping indicated at 122 in Figure 7A. The die tube 58 may be used as a reaction force against the anchor body 54 while the actuation rod 64 is pulled the proximal direction causing the frangible point 120 to sever. The final configuration is seen in Figure 2D.

As mentioned above, the exemplary structure for locking sutures relative to a body cavity may be utilized in a variety of anatomical environments. For instance, Figure 10 shows an alternative surgical technique for using a combined suture anchor 46' and anchoring structure 48' to repair a rotator cuff tendon 22. In this embodiment, rather than forming a blind cavity within the humeral head 24, the surgeon forms a cavity 130 that transects the greater tuberosity 28 and opens through the cortical layer 42 at both ends. After embedding the loop 32 of suture material within the rotator cuff tendon 22, the free ends 34a, 34b are inserted into and threaded through the cavity 130. The ends 34a, 34b are then passed through the lumen formed within the combined suture anchor 46' and anchoring structure 48', which combination is then inserted as shown into the cavity 130. The free ends 34a, 34b of suture are then tightened to the prescribed level and secured within the suture anchor 46'. It should be noted that the combined suture anchor 46' and anchoring structure 48' may be configured somewhat differently to permit the aforementioned tightening step, though the suture locking steps are preferably accomplished in the same manner as described above; namely, with a suture locking plug compressing the length of suture within the suture anchor 46'. Furthermore, the anchoring structure 48' contacts the exterior of the cortical bone rather than the interior as described above.

Figure 11 illustrates an alternative suture anchor 140 of the present invention having a body cavity anchoring structure 142 on a proximal end. A length of suture is shown having a loop 144 and a pair of free ends 146a, 146b

passing through the anchoring structure 142 and through a lumen 148 of a generally tubular body 150 of the suture anchor 140. In a distal portion of the tubular body 150, the free ends 146a, 146b pass out of the lumen 148 through a first aperture 152a and re-enter the lumen through a second aperture 152b located distally from the first aperture. As illustrated, the lumen 148 in the region of the apertures 152a, 152b is only partly defined by a semi-cylindrical extension of the tubular body 150, but other arrangements having a more complete lumen at this location are within the scope of the present invention.

With reference to Figure 11B, the apertures 152a, 152b are shown to be rounded to reduce abrasion on the suture free ends 146a, 146b. In addition, the bridge portion 154 of the tubular body 150 that separates the apertures 152a, 152b defines a pulley structure, much like the pulley 70 (Figure 8B) described above in the earlier embodiment. That is, the suture free ends 146a, 146b can easily slide with respect to the bridge portion 154, especially because of the rounded corners, to permit tightening of the suture loop 144 prior to locking the length of suture within the tubular body 150. The length of suture may be locked within the tubular body 150 using a locking plug as described above, or with another similar expedient.

Accordingly, although an exemplary embodiment of the invention has been shown and described, it is to be understood that all the terms used herein are descriptive rather than limiting, and that many changes, modifications, and substitutions may be made by one having ordinary skill in the art without departing from the spirit and scope of the invention. In particular, it is noted that the procedures, while oriented toward the arthroscopic repair of the rotator cuff, are applicable to the repair of any body location wherein it is desired to attach or reattach soft tissue to bone, particularly using an arthroscopic procedure.